1. Device identification and general information

1.1. Device trade name(s):

EGYSORB

1.2. Manufacturer's name and address:

TAISIER-Med SAE, 1st Industrial Zone- Block 13023-St.100-Building No.8-P.O Box 29- El Obour City –Zip Code 11828 – Cairo - Egypt

1.3. Manufacturer's single registration number (SRN):

EG-MF-000013855

1.4. Basic UDI-DI: *20144EGYSORBCH*

As our products are legacy devices we are depending on GS1 code

10CD1250	6222014494604
12CD1200	6222014407710
6CD1000	6222014495083
6CD1100	6222014497186
6CD1250	6222014494383
6CD1300	6222014494390
CD1000	6222014407697
CD1100	6222014407703
CD1200	6222014407710
CD1250	6222014407727
CD1300	6222014407734
FD1024RC	6222014494420
FD1124RC	6222014494451
FD1223RC	6222014494444
FD1322RC	6222014494437
GD1124RC	6222014495199
HD1023	6222014495052
HD1024	6222014497438
HD1025	6222014407796
HD1028	6222014495694
HD1120	6222014493737
HD1121	6222014491948
HD1122	6222014491931
HD1123	6222014495168
HD1124	6222014497483
HD1125	6222014493430
HD1127	6222014491924
HD1128	6222014495564
HD1221	6222014491993

HD1223	6222014495700
HD1224	6222014491986
HD1225	6222014491979
HD1227	6222014491962
HD1228	6222014491955
HD1269	6222014494505
HD1271	6222014494475
HD1272	6222014408052
HD1273	6222014493447
HD1274	6222014495373
HD1318	6222014494512
HD1323	6222014495175
LD1022	6222014492648
MD1020	6222014407741
MD1021	6222014407758
MD1021N	6222014493089
MD1022	6222014407765
MD1023	6222014407772
MD1024	6222014407789
MD1025	6222014407796
MD1027	6222014407802
MD1028	6222014407819
MD1120	6222014407826
MD1121	6222014407833
MD1122	6222014407840
MD1123	6222014407857
MD1124	6222014407864
MD1125	6222014407871
MD1126	6222014499265
MD1127	6222014407888
MD1128	6222014407895
MD1133	6222014493485
MD1134	6222014493492
MD1220	6222014495311
MD1221	6222014407901
MD1222	6222014407918
MD1223	6222014407925
MD1224	6222014407932
MD1225	6222014407949
MD1227	6222014407956
MD1228	6222014407963
MD1258	6222014407970
MD1259	6222014407987
MD1260	6222014493072
MD1266	6222014407994
MD1266N	6222014493690
MD1267	6222014408007
MD1268	6222014408014
MD1268D	6222014493881

MD1269	6222014408021
MD1270	6222014408038
MD1271	6222014408045
MD1272	6222014408052
MD1273	6222014408069
MD1274	6222014408076
MD1275	6222014408083
MD1276	6222014408090
MD1276TC	6222014494260
MD1277	6222014408106
MD1278	6222014408113
MD1279	6222014408120
MD1279D	6222014493898
MD1279N	6222014408120
MD1306	6222014492624
MD1307	6222014408137
MD1316	6222014408144
MD1317	6222014408151
MD1318	6222014408168
MD1319	6222014408175
MD1320	6222014499272
MD1321	6222014408182
MD1322	6222014408199
MD1323	6222014408205
MD1323VB	6222014494772
MD1324	6222014408212
MD1325	6222014408229
MD1326	6222014408236
MD1327	6222014408243
MD1328	6222014408250
MD1329	6222014499289
MD1406	6222014408267
MD1411	6222014408274
MD1412	6222014408281
MD1416	6222014408298
MD1417	6222014408304
MD1418	6222014408311
MD1419	6222014408328
MD1421	6222014408335
MD1422	6222014408342
MD1423	6222014408359
MD1424	6222014408366
MD1425	6222014493362
MD1426	6222014408373
MD1427	6222014408380
MD1428	6222014408397
MD1429	6222014408403
MD1506	6222014408410
MD1513	6222014408427

MD1514	6222014408434
MD1517	6222014408441
MD1518	6222014408458
MD1522	6222014408465
MD1523	6222014408472
MD1524	6222014408489
MD1525	6222014408496
MD1526	6222014493638
MD1527	6222014493287
MD1612	6222014408502
MD1613	6222014408519
MD1614	6222014408526
MD1615	6222014408533
MD1616	6222014408540
MD1617	6222014408557
MD1618	6222014408564
MD1618PN	6222014499081
MD1623	6222014408571
MD1624	6222014408588
MD1636SP	6222014493645
SD1000	6222014408595
SD1100	6222014408601
SD1200	6222014408618
SD1250	6222014408625
SD1300	6222014408632
XD1000	6222014408649
XD1100	6222014408656
XD1200	6222014408663
XD1250	6222014408670
XD1300	6222014408687

EMDN CODE: H0101010201 (POLYGLYCOLIC ACID MULTIFILAMENT)

1.5. Medical device nomenclature description / text:

POLYGLYCOLIC ACID MULTIFILAMENT.

1.6. Class of device: III

1.7. Year when the first certificate (CE) was issued covering the device:

2008

1.8. Authorized representative if applicable; name and the SRN:

- Qualitech International B.V.

- NL-AR-000002908

1.9. NB's name (the NB that will validate the SSCP) and the NB's single Identification number:

HTCERT, CE2803

2. Intended use of the device

2.1. Intended purpose:

EGYSORB sutures are intended for use in general soft tissues approximation &/or ligation including ophthalmic surgery.

2.2. Indication(s) and target population(s):

All surgical suture are surgical device that can be used in wide verities of surgeries with wide patient population (Sex, age, race,….etc) regarding the surgeon experience as stated in the IFU .

2.3. Contraindications and/or limitations:

As all absorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.

3. Device description

3.1. Description of the device:

EGYSORB is a sterile synthetic absorbable suture based on polyglycolic acid.

EGYSORB coated with polycaprolactone and calcium stearate. The sutures are available dyed violet D&C#2 (CI 60725)
EGYSORB complies with the requirement of USP and EP.

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences:

There is no previous generations or variants.

3.3. Description of any accessories which are intended to be used in combination with the device:

Stainless steel needle used as an accessory.

- Needle Functional Description
  It is an accessory to facilitate the penetration of thread through the tissue

3.4. Description of any other devices and products which are intended to be used in combination with the device:

EGYSORB don't likely to be combined with other medical devices

4. Risks and warnings

4.1. Residual risks and undesirable effects

-Edema because of using of suture under over stress by surgeon

-Loose stitches because of the user may be unfamiliar with surgical procedure technique of absorbable sutures

-Incisional herniation, Failure of approximation because of Closure of the site which may undergo expansion, stretching or distension

-Suture extrusion & delayed absorption because of Implementation of sutures in tissues with poor blood supply

-Erythema &indurations because of Absorption process of Subcuticular sutures

-Crushing or crimping damage of sutures because of Handling of sutures by application of surgical instrument such as forceps

-Damage of the needle causing problems to the patient because of Miss- handling of surgical needles (seeREF 24, 27, 28, 29, 30, 31, 32&33)

-Grasping in the point area may lead to Impair the penetration performance& cause fracture of the needle or cause bending or breakage reshaping needles may cause them to lose strength & be less resistant because of Grasping at the butt or attachment end

-Inadvertent needle stick injury, serious contamination to all persons dealing with the product because of Used needles due to Lack of exercise when handling surgical needles

-Inadequate Choice of suture type or material in case of Skin sutures which cause allergic reaction and remain in place longer than 7 days

-Wound contamination because of contaminated instrument or dressing (seeREF6&9)

-Failure of uses, because of Mal selecting of suture type (use of absorbable suture where extended approximation of tissue under stress is required) (seeREF5, 6, 9&22)

-Wound dehiscence which may vary with site of application & suture material used because of Use in elderly & mal- nourished or debilitated patient seeREF (5, 6, 16)

-Non sterile product, cause microbial infection to the patient, suture will lose tensile strength that be degraded before recommended period because of Opened or damaged package (see REF24&25)

-The safety and effectiveness of EGYSORB sutures in cardiovascular and neurological tissues have not been established. (See REF29)

4.2. Warnings and precautions

Under certain circumstances, notable procedures, immobilization of joints by external support may be employed at the discretion of surgeon.

As the risk of wound dehiscence may vary with the suture material and site of application. Surgeon should be familiar with surgical procedures and techniques involving absorbable sutures before using EGYSORB for wound closure.

The safety and effectiveness of EGYSORB sutures in cardiovascular and neurological tissues have not been established.

Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limit may lead to suture damage.

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

EGYSORB sutures require the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experiences of the surgeon. Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed (as all absorbable sutures a non-absorbable suture may be used for wounds under stress as extra support).

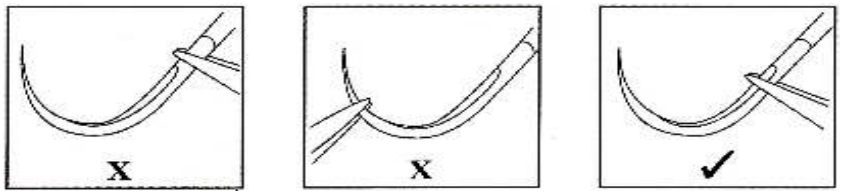
Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as sutures extrusion and delayed absorption may occur.

Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process.

This suture may be inappropriate in elderly, malnourished, debilitated patients, or in patients suffering from conditions which may delay wound healing.

When handling this or any other suture material, Care should be taken to avoid damage during the application of surgical instruments such as forceps or needle holders.

Care should be taken during the holding of the needle by needle holder, so grasp the needle in an area 1/3 to 1/2 of the distance from the attachment end to the point otherwise the needle may be fractured or break.



All needles are magnetizable and should therefore not be used in an active magnetic field. The users should exercise caution when handling the surgical needles to avoid inadvertent needle injury.

4.3. Other relevant aspects of safety, including a summary of any field safetycorrective action (FSCA including FSN) if applicable

Until now there is no incidents cases have been reported No regulatory actions taken by competent authority with various country where product sold in and we had made clinical search upon adverse events of predicate product from MAUDE & MHRA data bases.
Until now the product consider safe according to the preclinical studies &the post marketing clinical follow up carried on the product itself, also the clinical evaluation carried on equivalent brands & predicate device.

-No Incidents
-No FSN
-No Recall
-No PSR
-No warning

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

Requirement on Safety (MDD ER1):

Precaution should be taken in using PGA suture or any other absorbable suture where

Extended approximation of tissue under stress is required due to gradual loss of tensile strength with absorption (seeREF5, 6, 9&22).

As per (REF 5)

Incidence of wound dehiscence and herniation: total 8.1 %, not significantly different

Infection and sinus formation: total 10.6%, not significantly different

So we stated that

Being absorbable may induce higher percent of Incidence of wound dehiscence and herniation when used to approximate tissue that under stress so contraindication is added to the IFU: As allabsorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.See Risk reference no (6.2.1) & (6.2.3) At FMEA

As per (REF 6)

*Wound observation

-Wound dehiscence: 1, 1, 0

-Incisional hernia due to failure of suture technique: 4, 4, 2

-Incisional hernia due to deep wound sepsis: 1, 4, 3

So we state that

Being absorbable may induce higher percent of Incidence of wound dehiscence andHerniation when used to approximate tissue that under stress so contraindication is added to the IFU:

As all absorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.See Risk reference no (6.2.1)& (6.2.3) At FMEA

Also due to the risk of wound infection warning added to the IFU:

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.See Risk reference no (6.1.9)& (6.2.2) At FMEA

As per (REF 9)

Infection: significantly more in the case of Dexon(6vs. 0)

*later follow-up (6months): significantly higher incidence of incisional hernia(4vs. 0)

So we state that

Being absorbable my induce higher percent of Incidence of wound dehiscence andHerniation when used to approximate tissue that under stress so contraindication is added to the IFU:

As all absorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.See Risk reference no (6.2.1)& (6.2.3) At FMEA

Also due to the risk of wound infection warning added to the IFU:

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.See Risk reference no (6.1.9)& (6.2.2) At FMEA

-Acceptable surgical practice should be followed with respect to drainage and closure of

Infected wounds (seeREF6&9).

As per (REF 6)

*Wound observation

-Wound dehiscence:1,1,0

-Incisional hernia due to failure of suture technique: 4,4,2

-Incisional hernia due to deep wound sepsis: 1, 4,3

So we state that

Being absorbable may induce higher percent of Incidence of wound dehiscence andHerniation when used to approximate tissue that under stress so contraindication is added to the IFU:

As all absorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.See Risk reference no (6.2.1)& (6.2.3) At FMEA

Also due to the risk of wound infection warning added to the IFU:

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.See Risk reference no (6.1.9)& (6.2.2) At FMEA

As per (REF 9)

Infection: significantly more in the case of Dexon(6vs. 0)

*later follow-up (6months): significantly higher incidence of incisional hernia(4vs. 0)

So we state that

Being absorbable may induce higher percent of Incidence of wound dehiscence andHerniation when used to approximate tissue that under stress so contraindication is added to the IFU:

As all absorbable sutures EGYSORB is contraindicated where extended approximation of tissue under stress is required.See Risk reference no (6.2.1)& (6.2.3) At FMEA

Also due to the risk of wound infection warning added to the IFU:

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.See Risk reference no (6.1.9)& (6.2.2) At FMEA

-Needle detachment appears to be the most common adverse event in the PGA suture which could be treated in the design stage by:

Increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope. (See REF 24, 27, 28, 29, 30, 31, 32&33).

As per (REF 24)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: samples received: 1 open pouch, used sample; needle detached from thread. There are no previous complaints of this code/batch. There are no units in OEM stock. The used needle displays damage in the attachment are due to handling. The steel has been deformed by the needle holder and as result; the thread is broken inside the needle holder in the attachment area. Without any closed sample we cannot carry out a proper analysis. Needle attachment results before releasing the product were within specification. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfilled OEM requirements.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7)At FMEA

As per (REF 27)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: samples received: 21unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. Tested the needle attachment of the closed samples received and the results fulfill the requirements of the OEM. Reviewed

the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope. See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 28)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

U. S. Reporting agent notified on: (b)(4)2014. Manufacturing site evaluation: samples received:

13 unopened and1open pouch. There are no previous complaints of this code/batch. There are no units' inoem stock. Received 13 closed samples and 1 open and used sample with the needle detached from the thread. Tested the needle attachment of the closed samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope. See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 29)

The complaint is not corresponding (not justified). Action son

Product: not applicable. Corrective/preventative actions: not applicable.

So we state that

Us reporting agent notified on (b) (4)2014.Mfg site evaluation: samples received: none. There are no previous complaints of this code/batch. There are no units in OEM stock. Without samples, testing cannot be performed in order for proper analysis. Reviewed the batchmfg record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Actions on product: not applicable. Corrective/preventative actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope. See Risk reference no (2.13.5)&(2.13.6)& (2.13.7) At FMEA

As per (REF 30)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Us reporting agent notified on (b)(4)2014.Manufacturing site evaluation: samples received:130 unopened and 1open pouch. There are no previous complaints of this code/batch .There are no units in OEM stock. We have received 130 closed samples and 1open and unused sample. All closed packs received are tight. Tested the knot pull tensile strength of the closed samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 31)

The complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

So we state that

Us reporting agent notified on (b) (4) 2014. Manufacturing site evaluation: samples received: 36 unopened pouches. There are no previous complaints of this code/batch. There are no unit's inoem stock. All closed packs received are tight. Tested the knot pull tensile strength of the closed samples received and the results fulfill the requirements of the oem. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill oem requirements: final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 32)

The complaint is corresponding (not justified). Corrective/Preventive actions: not applicable.

So we state that

Us reporting agent notified on 06/20/2014.Mfgsiteeval:samples received: 188 unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. All packs received are tight. Test the knot pull tensile strength of the samples received and the results fulfil the requirements of the OEM. Review the batch mfg. record, this product had a normal process fulfill OEM requirements. Final conclusion: the complaint is corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 33)

The complaint is not corresponding (not justified).

Actions on product: not applicable.

Corrective/preventive actions:Not applicable.

So we state that

Samples received: 7 unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. All packs received are tight. Tested the knot pull tensile strength and needle attachment strength of the samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfilled OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Actions on product: not applicable. Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

The standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experiences of the surgeon.

-Also the break of the suture itself during use which is mainly due to over stretch during stitching and should be addressed in the IFU:

Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage. (See REF24&25)

As per (REF 24)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: samples received: 1 open pouch, used sample; needle detached from thread. There are no previous complaints of this code/batch. There are no units in OEM stock. The used needle displays damage in the attachment are due to handling. The steel has been deformed by the needle holder and as result; the thread is broken inside the needle holder in the attachment area. Without any closed sample we cannot carry out a proper analysis. Needle

attachment results before releasing the product were within specification. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfilled OEM requirements.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 25)

The complaint is not corresponding (not justified).Action son

Product: not applicable. Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: none. As no batch number is available, the batch manufacturing record cannot be reviewed. Without closed samples and/or defective samples a proper analysis cannot be performed. Final conclusion: the complaint is not corresponding (not justified). Actions on product: not applicable. Corrective/preventive actions: not applicable.

This event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage .See Risk reference no (6.1.10)At FMEA

As per (REF 72)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 73)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 74)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 75)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 76)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on

our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

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-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 78)

Degraded and unusable upon removal from the foil pouch due to exposed environmental conditions during transit and storage, compromising sterility.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as transportation conditions so:

The risk of environmental conditions in transportation and storage is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

- Transportation validation report (QA-Pr-07-184/F1)

- Data logger reading records

RISK REFF NO 6.3.1

As per (REF 79)

Complaints have been received with allegations of Incorrect Needle Curvature.

So we state that

The risk of Incorrect Needle Curvature it is maybe due to mixture between different codes is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

- line clearance traing record the operator &IPC supervion

RISK REFF NO 2.13.3 At FMEA

As per (REF 80)

No suture type can be considered the 'best treatment' for the prevention of surgical site infection, hernia, wound dehiscence and sinus/fistula occurrence.

So we state that

The literature shows that in comparison of polyglycolic acid with nylon the only favor of nylon is a reduction in the rate of incisional hernias, that is due to the nature of nylon as it is a non-absorbable suture material so there is no loss of tensile strength so the rate of wound dehiscence is low but the nature of polyglycolic acid is absorbable suture material which is susceptible to gradual loss of tensile strength as follow:

	Retaining Strength	Loss
At Implantation	As USP &EP	Zero
After 2 Weeks	70 %	30 %
After 3 Weeks	45-50 %	50-55 %
After 4 Weeks	20-25 %	75-80 %
After 5 Weeks	0%	100%

So according this gradual loss of tensile strength the rate of wound dehiscence is higher,

As the risk of wound dehiscence may vary with site of application & suture material used

Note in the pamphlet:

Surgeon should be familiar with surgical procedures and techniques involving absorbable sutures before using EGYSORB for wound closure.

See risk ref. (6.2.1)

As per (REF 83)

The literature shows that in comparison of PGA with silk and nylon, it is found to be better in the physical characteristics such as tensile strength.

So we state that

The literature shows that in comparison of PGA with silk and nylon, it is found to be better in the physical characteristics such as tensile strength.

According to the nature of multifilament suture material it is more rough and more susceptible to bacterial accumulation than monofilament suture material

So we state an Awareness of medical stuff for how to deal with infected wound

Note in the pamphlet:

Warning that acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. see risk ref. (6.1.9)

Conclusion:

The above data ensure that the EGYSORB not cause any hazards toward surgeons, medical staff or third parties.

Requirement on Performance (MDR SPR7):

The above data in sure the effective performance of PGA suture in general soft tissue approximation and ligation like in skin closure(seeREF2,7,17,18&23&70&71&72)

As per (REF 2)

1-Degree of wound appearance at 2-3days: little difference between the numbers of wounds

2-Degree of wound appearance at 7-10 days: similar trend in wound used dexon, polyethylene, nylon .Less normal appearance in silk suture (no statistical difference)

*Dexon show no harmful inflammation or side effect

So we state that

This indicates the safe effective use of EGYSORB in approximation of skin with no complications

As per (REF 7)

PGA suture showed significantly lower incidence of inflammatory reaction. Difference as suturingregion. Women had a higher incidence of suppuration where silk was used.

So we state that

This indicates the safe effective use of EGYSORB in approximation of skin with no complications and better support.

As per (REF 17)

1) Mechanical properties: superior strength and good handling property

2) Healed without evidence of inflammation, drainage, and infection.

3) PGA sutures provoke very minimal inflammatory reaction.

So we state that

The mechanical properties and biological inertness make the PGA suture effective and safe in wide range of surgical operations.

As per (REF 18)

No statistical difference between suture groups

So we state that

There is no statistical difference in infection degree of wounds on using different suture material although being synthetic yet on suturing with PGA wound treatment should be adequate so warning added to the IFU:

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. See Risk reference no (6.2.1)At FMEA

As per (REF 23)

Various mechanical properties: excellent in all sizes of the suture material

Very little tissue response and infection

So we state that

PGA suture proved to be an excellent inert absorbable synthetic suture that can be usedsafely in different surgical operations

As per (REF 70)

Our findings indicate, that Novosyn® Quick is safe and reliable for skin closure in adults and paediatric patients and can be regarded as a viable alternative to Vicryl® Rapide.

So we state that

PGA is approved to be safe in skin closure in adults and pediatric Patients

As per (REF 71)

Amongst the different classes of biodegradable polymers, thethermoplastic aliphatic poly(esters) like poly(lactide) (PLA), poly(glycolide) (PGA), and especially the copolymer of lactide and glycolide, poly(lactide-co-glycolide) (PLGA) have generated immense interest due to their favorable properties such as good biocompatibility, biodegradability, and mechanical strength. Also, they are easy to formulate into different devices the utility of these polymers to make sutures/"bers [2,3,5,12]. These "bers had several advantages like good mechanical properties, low immunogenicity and toxicity, excellent biocompatibility, and predictable biodegradation kinetics

So we state that

The previous literature address safety use of PGA polymer as a suture, as it has mechanical properties, low immunogenicity and toxicity, excellent biocompatibility, and predictable biodegradation kinetics,

Which address that our product EGYSORB considered as state of art.

-ophthalmic surgery (seeREF8)

As per (REF 8)

No significance between Dexon, silk, and collagen.

Dexon sutures are very strong and knots hold well.

Dexon absorbed in 5 weeks on average, no serious adverse reactions.

Dexon is suitable and safe for use in ophthalmic surgery.

So we state that

This indicates the safe effective use of EGYSORB in ophthalmic surgery with better knotsecurecharacters

-abdominal closure (seeREF1, 4, 11, 13, 14, 16, 19&20)

As per (REF 1)

1) Gross observation: almost no inflammatory reaction

2) Microscopic observation:

-No change in all patients. Negative on patchtest and his taminetest.

-Good tolerance with no dehiscence or infection of the wound

-No fistulas, stenosis

-Stitches in the skin were usually removed between the fifth and seventh days

So we state that

This indicates the safe effective use of EGYSORB in approximation of abdominal wall with no post-operative complications.

As per (REF 4)

-Over all incidence of dehiscence:

2/347(=0.58%).No difference betweenDexon and prolene

-Infection: no difference Dexon: 19/180(11%) Prolene: 13/167(7.8%)

-Late follow-up of hernia:265 patients after

6 months. No difference Dexon: 8 (6.1%) Prolene: 7(5.2%)

So we state that

There is no significant difference in using PGA suture for abdominal closure comparing toPolypropylene which indicates the safe effective use of EGYSORB in approximation of abdominal wall.

As per (REF 11)

Dehiscence: not significantly different Suture-granuloma: lower in case with Dexon Wound infection: similar trend with conventional suture materials

So we state that

This indicates the safe effective use of EGYSORB in approximation of abdominal wall with noPost-operative complications.

As per (REF 13)

-Frequency of wound rupture: 1.3%. No significant difference between Dexon and Mersilene groups

-Frequencyofincisionalhernia: 2.3%.No significant difference

-Suture granuloma: 9.0 %. All for Mersilene groups

So we state that

No significant different were found regarding the wound rapture and incisional hernia butPGA suture show lower degree in suture granuloma which indicated the advantage in use in primary laprotmies.

As per (REF 14)

1-Degree of scar formation: Statistically different

DSS: grade 0(25), grade1(15), grade2 (4)

SPS:grade0(16),grade1(20),grade2 (8)

2-Hypertrophy:nodifference

3-Breadth: statistically different

-less after SPS

4-Cosmetic result: no difference

So we state that

The degree of scare formation is higher in case of PGA suture which may be due to the inflammatory reaction associated with the absorption process so warning is added to theIFU:

Sutures should be placed as deeply as possible to minimize the erythema and in duration normally associated with the absorption process.See Risk reference no (6.1.13)At FMEA

As per (REF 16)

Continuous synthetic sutures can be used effectively.

So we state that

This indicates the safe effective use of EGYSORB in peritoneum, subcutaneous tissue, skin in abdominal midline incision

As per (REF 19)

1) Toxicity studies: ten patients. Results were within expected limits

2) Handlingproperties and technical considerations: stronger, similar knot holding quality to that of silk, cat gut and cotton, and superior to that of nylon, Dacron or other synthetic sutures

3) Wound complications: different amount of infection according as the status of wounds (contamination or related).

4) Systemicor unrelated complications: not related.

So we state that

This indicates the suitability of the PGA sutures for use in a wide variety of surgical

Operations: proper mechanical properties, not interfering wound healing.

As per (REF 20)

No significant differences in the incidence of series infections were foundbetween silk and polyglycolic acid, however, a significant difference inthe occurrence of suture fistulas.

So we state that

Polyglcolic acid or other absorbable suture materials are recommended for closure of thegelea, subcut is fascia and muscle

-and episiotomy and inguinal repair (seeREF3,10,12,15&21) .

As per (REF 3)

Chromic catgut slightly more uncomfortable

No difference in degree of inflammation

So we state that

This indicates that the use of EGYSORB in episiotomy repair is superior to the commonly used catgut

As per (REF 10)

*Edema and bruising: no significant difference

*Pain atrest: lower severity of pain In PGA

Group (no statistical difference)

*Pain on movement: lower severity of pain in PGA group(no statistical difference)

*Use of analgesics: fewer patients wanted analgesics(significantly different)

So we state that

This indicates that the use of EGYSORB in episiotomy repair is superior to the commonly used cat gut.

As per (REF 12)

1-arly wound complications: Mersilene 7% ,Dexon 5%

2-Later Complications

-Hernia recurrence: similar in both groups(mersilene5.1%, Dexon4.9%)

-Neuralgia: no difference

-Testicular complications: no difference

-Suture fistula: only one in Mersilene group

So we state that

This indicates the safe effective use of EGYSORB in repair of inguinal hernia

As per (REF 15)

One recurrence of hernia in each group

No suture granuloma as developed in either group

So we state that

This indicates the safe effective use of EGYSORB in repair of inguinal hernia.

As per (REF 21)

-No evidence of disruption of anastomosis nor has re-exploration been necessary

-no excessive drainage of urine frompyelotomies, uretrotomies, or vasectomies

-calculus formation has not occurred in any patient

So we state that

PGA suture is superior to other absorbable sutures for use in urogenital operations with excellent tensile strength, minimal tissue reaction, lack of calculus formation, superior handling characteristics and excellent knot security.

As per (REF 80)

No suture type can be considered the 'best treatment' for the prevention of surgical site infection, hernia, wound dehiscence and sinus/fistula occurrence.

So we state that

The literature shows that in comparison of polyglycolic acid with nylon the only favor of nylon is a reduction in the rate of incisional hernias, that is due to the nature of nylon as it is a non-absorbable suture material so there is no loss of tensile strength so the rate of wound dehiscence is low but the nature of polyglycolic acid is absorbable suture material which is susceptible to gradual loss of tensile strength as follow:

	Retaining Strength	Loss
At Implantation	As USP &EP	Zero
After 2 Weeks	70 %	30 %
After 3 Weeks	45-50 %	50-55 %
After 4 Weeks	20-25 %	75-80 %
After 5 Weeks	0%	100%

So according this gradual loss of tensile strength the rate of wound dehiscence is higher,

As the risk of wound dehiscence may vary with site of application & suture material used

Note in the pamphlet:

Surgeon should be familiar with surgical procedures and techniques involving absorbable sutures before using EGYSORB for wound closure.

See risk ref.(6.2.1)

As per (REF 81)

Mediolateral episiotomy is the method of choice in France. However, the procedure for this technique should be studied more. Subcuticular technique with an absorbable synthetic material may be the optimal method of repair.

So we state that

PGA is approved to be safe in use in Subcuticular technique as a method of repair of Mediolateral episiotomy.

Conclusion:

Based on the above data which is done for predicate device (DaxonII & Safil), we insure the safety use of PGA suture in general soft tissue approximation or ligation like in skin closure. So, we can consider our product EGYSORB is safe and effective device for that intended use being equivalent to (DaxonII & Safil), according to comparison study stated in point (6.2) in this CER

Requirement on Acceptability of Side-effects (MDR SPR8):

Residual risks such as (inflammatory reaction and erythema) are associated with foreign body (see ref 68&69&72) that may happen with suture or any other foreign body, which is consider a normal side effect & still acceptable against the benefits of suture in approximation & ligation of tissue and wound healing .

As per (REF 68)

Even if until now there were no reported foreign body reactions developed to PGA suture used for closing the duramater after resection of a brain tumor, these reactions may occur and they are difficult to distinguish, both clinically and radiologically, from glioblastoma relapse. However, if brain imaging and clinical aspects become suggestive for tumor recurrence or radiation necrosis, the neurosurgeons should include the foreign body reactions into the differential diagnosis of the lesion. In addition, it is indicated a new operation to determine the true nature of that space-occupying lesion, but at the same time, it can add

an extra few months in the life of the patients who were already treated with 5-ALA-guided resection, because it allows a wide resection of the tumor with positive prognosis.

So we state that

Even the literature address no reported foreign body reactions developed to PGA suture used for closing the duramater after resection of a brain tumor which may assure the safety of the product , yet for more safety we stated that the EGYSORB may cause any foreign body reactions

There is a referring in the IFU:

As all absorbable sutures EGYSORB may cause minimal adverse reactions include inflammatory tissue reaction, localized irritation and wound separation. See risk reference no.(6.2.4) At FMEA

As per (REF 69)

Biodegradable materials are a good option in capsuloligamentoufixation, with multiple advantages and a low incidence of complications. However, hand surgeons should be aware of the possibility of late foreign-body reactions that could be especially severe in carpal bones.

So we state that

The previous literature address safety use of PGA in capsuloligamentous fixation, and the risk of foreign-body reactions had been addressed in risk assessment (see risk reference no.6.2.4 at QA-Pr-07-43/F8) of the product and there is a referring in the IFU:

WARNINGS & PRECAUTIONS:

Surgeon should be familiar with surgical procedures and techniques involving absorbable sutures before using EGYSORB for wound closure. See risk reference no.(6.2.1)&(6.2.4) At FMEA

ADVERSE REACTIONS:

As all absorbable sutures EGYSORB may cause minimal adverse reactions include inflammatory tissue reaction, localized irritation and wound separation. See risk reference no.(6.2.4) At FMEA

As per (REF 71)

Polyglycolic acid (PCA) is a tough, fibre-forming polymer and has been used to produce synthetic absorbable sutures since the early 1960s.

Polyglycolic acid sutures elicit a significant foreign body inflammatory response proportional to suture gauge. This reaction may be minimized by early suture removal. The study validates a novel and ethical approach to the examination of human skin response to implanted suture material

So we state that

The previous literature address safety use of PGA polymer as an absorbable sutures since 1960s which assure that our product EGYSORB considered as state of art.

For the eliciting of foreign body inflammatory response or reaction, there is a referring in the IFU:

ADVERSE REACTIONS:

As all absorbable sutures EGYSORB may cause minimal adverse reactions include inflammatory tissue reaction, localized irritation and wound separation.

WARNINGS & PRECAUTIONS:skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed See risk reference no.(6.2.4) At FMEA

See section6.6.2. Risk benefits analysis

As all absorbable sutures EGYSORB may cause minimal adverse reactions include inflammatory tissue reaction, localized irritation and wound separation.

Conclusions

From the above clinical data retrieved from different adverse events it's clear that the overall benefits of using PGA surgical suture still outweigh the risks which a raised.

All data and information regarding uses and safety is provided to the user through IFU and shall be followed up during in the post marketing surveillance of the product.

This clinical evaluation is continues operation and on any new finding it should be updated.

There is a comparison study had been performed between our product and the equivalent predicate product which is already in the market with well-established knowledge of state of art and by performing clinical search from different databases (PubMed, MAUDE, MHRA, MEDSUN), there is good evidence of the product performance and no serious adverse events that may counter the use of the product which is reflected in the risk benefit analysis, so our product is considered as state of art as wound closure device with the stated intended use .

So over all we can conclude That (EGYSORB) is a safe device for general soft tissue approximation or ligation like in skin closure.

5.2. Summary of clinical data from conducted investigations of the device beforethe CE-marking, if applicable:

Surgical sutures are exempted from clinical investigations as
All our products are common surgical products that have been introduced to the market under many brand names carrying CE mark (see the attached comparison table) for more than 20 years that make it easy to have a sufficient pre-clinical data through clinical literature and trials that had been carried out on equivalent brands that have exact same composition and intended use of our product, so our clinical evaluation mainly abound critical review of clinical literature redrafted from scientific data bases and adverse event published of equivalent product and this would be supported with post market follow up carried out on our product

5.3. Summary of clinical data from other sources, if applicable:

Post marketing data retraved from different data bases like (MAUDE,MEDSUN MEHRA and TPLC) related to equivalent devices.

1- MAUDE:

1.1 Requirement on Safety

As per (REF 24)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: samples received: 1 open pouch, used sample; needle detached from thread. There are no previous complaints of this code/batch. There are no units in OEM stock. The used needle displays damage in the attachment are due to handling. The steel has been deformed by the needle holder and as result; the thread is broken inside the needle holder in the attachment area. Without any closed sample we cannot carry out a proper analysis. Needle attachment results before releasing the product were within specification. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfilled OEM requirements.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7)At FMEA

As per (REF 27)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Manufacturing site evaluation: samples received: 21unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. Tested the needle attachment of the closed samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 28)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

U. S. Reporting agent notified on: (b)(4)2014. Manufacturing site evaluation: samples received:

13 unopened and1open pouch. There are no previous complaints of this code/batch. There are no units' inoem stock. Received 13 closed samples and 1 open and used sample with the needle detached from the thread. Tested the needle attachment of the closed samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 29)

The complaint is not corresponding (not justified). Action son

Product: not applicable. Corrective/preventative actions: not applicable.

So we state that

Us reporting agent notified on (b) (4)2014.Mfg site evaluation: samples received: none. There are no previous complaints of this code/batch. There are no units in OEM stock. Without samples, testing cannot be

Performed in order for proper analysis. Reviewed the batchmfg record, this product had a normal process

Andthe results during the process fulfill OEM requirements. Final conclusion: the complaint is not

Corresponding(not justified). Actions on product: not applicable. Corrective/preventative actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope. See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

As per (REF 30)

The complaint is not corresponding (not justified).

Corrective/preventive actions: not applicable.

So we state that

Us reporting agent notified on (b)(4)2014.Manufacturing site evaluation: samples received:130 unopened and 1open pouch. There are no previous complaints of this code/batch .There are no units in OEM stock. We have received 130 closed samples and 1open and unused sample. All closed packs received are tight. Tested the knot pull tensile strength of the closed samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 31)

The complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

So we state that

Us reporting agent notified on (b) (4) 2014. Manufacturing site evaluation: samples received: 36 unopened pouches. There are no previous complaints of this code/batch. There are no unit's inoem stock. All closed packs received are tight. Tested the knot pull tensile strength of the closed samples received and the results fulfill the requirements of the oem. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfill oem requirements: final conclusion: the complaint is not corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make 100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 32)

The complaint is corresponding (not justified). Corrective/Preventive actions: not applicable.

So we state that

Us reporting agent notified on 06/20/2014.Mfgsiteeval:samples received: 188 unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. All packs received are tight. Test the knot pull tensile strength of the samples received and the results fulfil the requirements of the OEM. Review the batch mfg. record, this product had a normal process fulfill OEM requirements. Final conclusion: the complaint is corresponding (not justified). Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

As per (REF 33)

The complaint is not corresponding (not justified).

Actions on product: not applicable.

Corrective/preventive actions:Not applicable.

So we state that

Samples received: 7 unopened pouches. There are no previous complaints of this code/batch. There are no units in OEM stock. All packs received are tight. Tested the knot pull tensile strength and needle attachment strength of the samples received and the results fulfill the requirements of the OEM. Reviewed the batch manufacturing record, this product had a normal process and the results during the process fulfilled OEM requirements. Final conclusion: the complaint is not corresponding (not justified). Actions on product: not applicable. Corrective/preventive actions: not applicable.

This risk of needle detachment may be overcome during design stage by increase the safety margin of needle attachment strength by doubling the pharmacopeia value and make100% manual pull testing and microscope.

See Risk reference no (2.13.5)& (2.13.6)& (2.13.7) At FMEA

About the suture break this event may be due to stretch of the suture above the limit of the tensile strength and that was showed as a caution for using the suture at the IFU: Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage.See Risk reference no (6.1.10)At FMEA

The standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experiences of the surgeon.

-Also the break of the suture itself during use which is mainly due to over stretch during stitching and should be addressed in the IFU:

Each USP size has its upper limits tensile strength (USP and EP), over stretch above this limits may lead to suture damage. (See REF24&25)

2- TPLC

As per (REF 72)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 73)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 74)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 75)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 76)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 77)

Issue on a specific packaging machine resulted in a hole in the primary packaging, product sterility compromised and could result in infection.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as packing so:

The risk of incomplete seal of inner pack is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

-Check temp.

-Calibration of machine sensors (PM-SOP-07-10)

-Visual inspection of Al pouches sealing (QA-WI-07-56)

-Packing Validation (QA-Pr-07-111)

-Leak testing (QC-SOP-07-96)

RISK REFF NO 2.8.7

As per (REF 78)

Degraded and unusable upon removal from the foil pouch due to exposed environmental conditions during transit and storage, compromising sterility.

So we state that

We accept this piece of information also it is not addressing the same product under evaluation, but it contains a common feature of the absorbable surgical suture family, which may reflect on our product such as transportation conditions so:

The risk of environmental conditions in transportation and storage is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

- Transportation validation report (QA-Pr-07-184/F1)

- Data logger reading records

RISK REFF NO 6.3.1

As per (REF 79)

Complaints have been received with allegations of Incorrect Needle Curvature.

So we state that

The risk of Incorrect Needle Curvature it is maybe due to mixture between different codes is addressed in risk assessment (QA-Pr-07-43/F8) and it covered by:

- line clearance traing record the operator &IPC supervion

RISK REFF NO 2.13.3 At FMEA

5.4. An overall summary of the clinical performance and safety

From the above clinical data retrieved from different adverse events it's clear that the overall benefits of using PGA surgical suture still outweigh the risks which a raised.

All data and information regarding uses and safety is provided to the user through IFU and shall be followed up during in the post marketing surveillance of the product.

This clinical evaluation is continues operation and on any new finding it should be updated.

There is a comparison study had been performed between our product and the equivalent predicate product which is already in the market with well-established knowledge of state of art and by performing clinical search from different databases (PubMed, MAUDE, MHRA, MEDSUN), there is good evidence of the product performance and no serious adverse events that may counter the use of the product which is reflected in the risk benefit analysis, so our product is considered as state of art as wound closure device with the stated intended use .

So over all we can conclude That (EGYSORB) is a safe device for general soft tissue approximation or ligation like in skin closure.

5.5. Ongoing or planned post-market clinical follow-up:

Over 217 cases randomly followed up EGYSORB suture only one case show inflammation due to delay in absorption in mal ntriationed kidney failure patient which is also addressed in the risk assessment of the product and stated as warning in the IFU: This suture may be inappropriate in elderly, malnourished, debilitated patients, or in patients suffering from condition which may delay wound healing.
Otherwise no adverse event during operation or post-operative noticed.

The product is safe to be used during surgical operation including general soft tissue approximation.

6. Possible diagnostic or therapeutic alternatives:

- **Therapeutic Alternative:**

These are probably the most commonly used alternative to suturing. Wound staples are made of steel and are rectangular, with an opening in the bottom. Staples provide a quick alternative for large scalp and trunk wounds.

Surgical glue may be appropriate where there is little or no wound tension.

Wound closure tapes are often helpful to support the wound following subcuticular closure, use of surgical glue, or after removal of epidermal sutures.

7. Suggested profile and training for users

Surgeon should be familiar with surgical procedures and techniques

8. Reference to any harmonized standards and CS applied

European pharmacopeia (EP 11)

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
Rev no. (1)	10/12/2025	Revision of SSCP according to MDCG 2019-9 and updated technical documentation	☑ Yes, Validation language: ENGLISH ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			☐ Yes Validation language: ☐ No

Quality Manager:-



Date: 10/12/2025