Instructions for Use

AcXess Skin Stapler

Disposable skin stapler with counter
(with regular or wide staples)

A Product of:
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Important
1. This device was designed, tested and manufactured for single patient use only.
2. Any attempt to re-use or reprocessing may lead to failure and potential patient injury.
3. Reprocessing and/or re-sterilization of this device may give rise to patient infection through contamination.
4. Do not re-use, reprocess or re-sterilize this device!

Description of disposable skin stapler:
A skin stapler is simply a mechanical device to evert the skin closure in a wide variety of surgical procedures.

Indications for use:
The device is used for routine closure in a wide variety of surgical procedures.

Directions for use:
1. With two tissue forceps, pick up each wound edge individually and approximate the edges. Or with one tissue forceps, force skin edges together until edges evert or apply tension to either end of the incision, such that the tissue edges which begin to approximate themselves are everted.
2. Position the instrument very lightly over the everted skin edges. Instrument should be held at a 35° angle to the skin.
3. Squeeze the trigger until the trigger motion is halted, then release the trigger and move the instrument backward.
4. If desired, before releasing the trigger, lift up on the instrument. This will help to evert the skin edges, which can then be more easily grasped with the tissue forceps. Release the trigger after the forceps are in place and repeat the sequence to fire the next staple.
5. At the end of use, the device must be disposed according to the safety instructions of your institution’s blood borne pathogens disposal policy. To reduce risk of contamination, avoid direct unprotected contact with used device. Used device must be destroyed through incineration.

Warnings and precautions:
1. Sterility guaranteed unless package has damaged or seal is broken.
2. Dispose of all fired instruments, DO NOT RESTERILIZE skin staplers. Re-sterilization may adversely affect the integrity of the instrument.
3. Read all instructions carefully. Failure to properly follow the instruction may lead to serious surgical consequences such as staple line disruption.
4. When it is not possible to maintain at least a 5mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated.
5. The trigger motion must be fully operated until it produces a click, otherwise the staple counter will not function normally.
6. WARNING: No modification of this equipment is allowed.

Storage and handling:
1. Device must be stored in a clean, cool, dry place. Storage temperature: -25°C to 55°C (transport temperature: -25°C to 70°C, relative humidity: 10% to 100%).
2. Atmospheric Pressure: 70 kPa to 106 kPa.
3. It must be handled with care to avoid damage to the packaging and its content during transportation and storage.
4. Device must not be in contact with acids or other corrosive liquids.

Staple dimensions:

<table>
<thead>
<tr>
<th>Reference Code</th>
<th>Specifications</th>
<th>Staple dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>KN.10.035.000</td>
<td>with 35 wide staples</td>
<td>wide: open: width 11.8mm, height 3.4mm</td>
</tr>
<tr>
<td>KN.10.025.000</td>
<td>with 25 wide staples</td>
<td>closed: width 8.8mm, height 4.0mm</td>
</tr>
<tr>
<td>KN.10.015.000</td>
<td>with 15 wide staples</td>
<td>regular: open: width 10.8mm, height 2.8mm</td>
</tr>
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<td>KN.20.035.000</td>
<td>with 35 regular staples</td>
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Explanation of symbols used on labelling:

Date of manufacture
Consult Instructions for use
Latex free
Storage temperature
Manufacturer

Use by / expiry date
For single use only
Keep away from sunlight
REF
Catalogue No.

Batch code
Do not resterilise
Keep dry
Authorised representative in the European Community

STERILE
Do not use if packaging is damaged
EC REP
Sufficient for

Modern Medical Equipment Mfg. Ltd.
Unit A, 11/F., Mali Wah Ind. Bldg.,
1-7 Wah Sing Street, Kwai Chung,
New Territories, Hong Kong.

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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