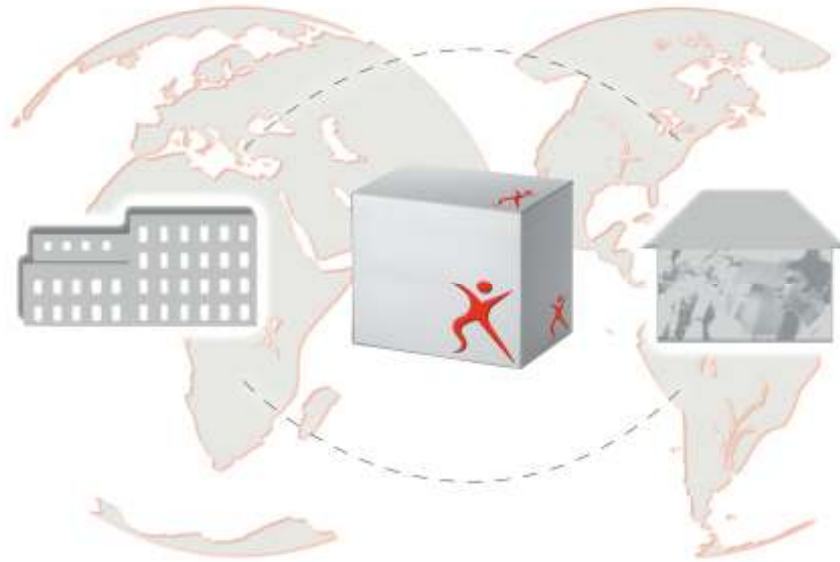




CaReS[®]-1S

**Administration
& Logistics**



STORAGE

- the CaReS[®]-1S implant must be stored at temperatures between 2°C and 25°C
- the CaReS[®]-1S implant must be stored flat as described outside the package
- the storage conditions have to be monitored





IDENTIFICATION

- **addresses of sender and receiver**, as well as direct communication data of **respective contact persons** and **int'l. advice stickers** must be visible outside the transport packaging.



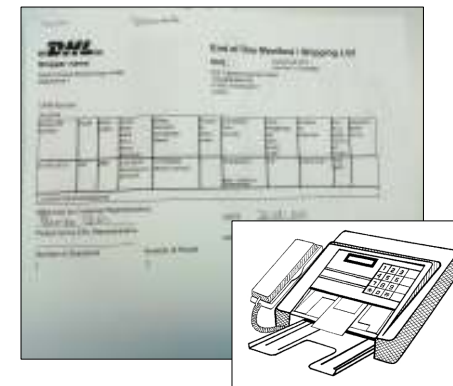
TRANSPORT

- during the shipment/transport of the CaReS[®]-1S the ambient temperature for the implant is between 2°C and 25°C.



NEVER below +2°C

- any shipment has to be **pre-announced** and **verified** by the recipient by mail or facsimile.





Labeling

- TOP: _____
Name of Manufacturer / Product Name /
Description of product / size in diameter
and height



- LATERAL: _____
storage position upside - Instructions
inside - storage temperature - Lot N° -
Expiration date - sterile - CE N° – Product
Reference Code



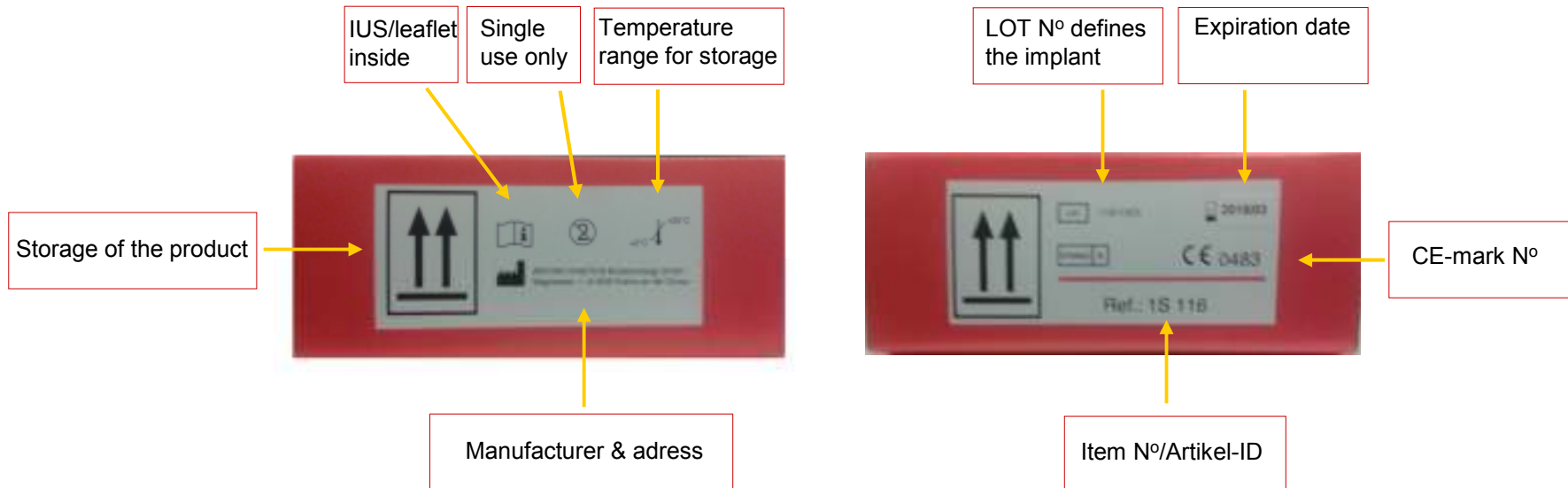
- BOTTOM: _____
Security label; product integrity





Labeling

(outer package/banderole)





BLISTER + Packaging

- BLISTER (primary packaging):
Product Name + size in diameter and height + Lot N°
- plastic packaging (secondary packaging):
AKI logo and adress of AKI (producer)
product name & size – storage temperature - Lot N° - Expiration date – sterile - CE N°
- RED DOT:
Proof of successful gamma irradiation



Also included is a leaflet with the instructions of use (IUS)



SEQUENCE

- CaReS-1S is a MEDICAL DEVICE class III product therefore one has to pay particular attention to the following matters:

Traceability of each single unit -
which means, you will have to ensure a possibility to always know who was the recipient of a certain unit of CaReS-1S

In case of unintended events,
the medical advisor of AKI has to be notified immediately

All and every study(ies) with/on the product
must be reported in advance to the medical advisor of AKI

Users must be trained in advance on the product and its applications. On a quarterly base,
Customer Service of AKI has to be informed on all attendances of such training and workshops.



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