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Issue Date: 10-15-2016

Version Data 4.00

Product Description

Expansion screws in various sizes.

REF NUMBER

Restrictions to use:

For use only by dental professionals.

| Manufacturer | : International Orthodontic Services | | | | |
|---------------------------------------|--|--|--|--|--|
| Address | : 12811 Capricorn St. Stafford, TX 77477 USA | | | | |
| Phone No, | : 1888-IOS-8882 (1888-461-8882) | | | | |
| Emergency Phone No, : +1 832 342 9487 | | | | | |

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MATERIAL AND COPMOSITIONS

| Stainless Steel Nickel - Silver Polyamide Polyethylene Palladium Gold | Cr = 17 - 19% Cu = 41 - 45% NH(CH2)5CO C2H4 Pd | • | -10% -11% | Mn= Zn= | 1 - 2% rest | Fe= | rest |
|--|--|-------|--------------|------------|----------------|-----|------|
| Gold | Au | | | | | | |

MECHANICAL DATA

| | Tensile Strength | Elongation A5 | Hardness | |
|-----------------|-----------------------------|---------------|-----------|--|
| Stainless Steel | 800 - 900 N/mm ² | 20% | 260 HV 10 | |
| Nickel- Silver | 250 - 300 N/mm ² | 9% | 90 HV 10 | |
| Polyamide | Not tested | Not tested | 62° Shore | |
| Polyethylene | Not tested | Not tested | 45° Shore | |

TOXICAL ACTION

none

ALLERGICAL ACTION

Persons who are allergic against nickel can get eruptions. Remedy: Stop therapy immediately.

DANGERS CAUSED BY THE PRODUCT

none

RISK OF FIRE

none

SAFTY DEVICES

not required

APPLICATIONS

Only for single use.

Device has to be built into the applicance of a dental technican.

A doctor has to overgrow the therapy.

The patient has to keep the appliance clean, especially the expansion screw. Tartar and lime can block the function of the screws.

QUALITY CONTROL

Inspection methods as specified in QM manual according ISO standards

QUALITY SYSTEMS

DINENISO9001:2000 DINENISO13485 Directive 93/42/EEC