

Hygienic Design

You can't make clean stuff with dirty machines



Hygienic Design

Making stuff clean is better than cleaning stuff

Sterilization methods:

- autoclaving – 135C, 15psi steam, up to 1hr
- H_2O_2
- Gamma Ray
- UV
- Ethylene Oxide
- Ozone

Hygienic Design

It isn't clean if you can't prove it's clean

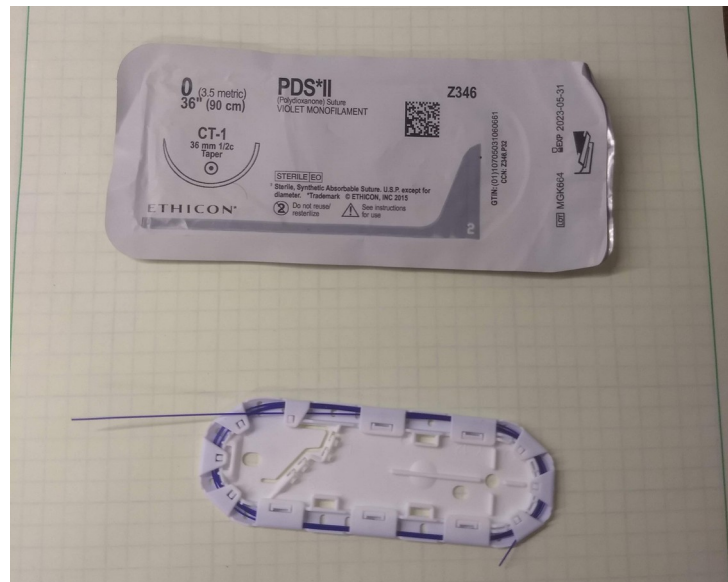
FDA:

- cGMP: (current) Good Manufacturing Practice
- 21 CFR Chapter I parts 1 to 1271
- Installation qualification (IQ)
- operational qualification (OQ)
- performance qualification (PQ)

Hygienic Design

Once it's clean, you've got to keep it clean

- packaging and distribution



Materials

- high temperature
- biocompatibility
 - bioinert
 - antimicrobial

Metals:

- stainless steel
- copper alloys

Polymers:

- silicone
- PTFE (Teflon)
- PEEK / Ultem
- polycarbonate

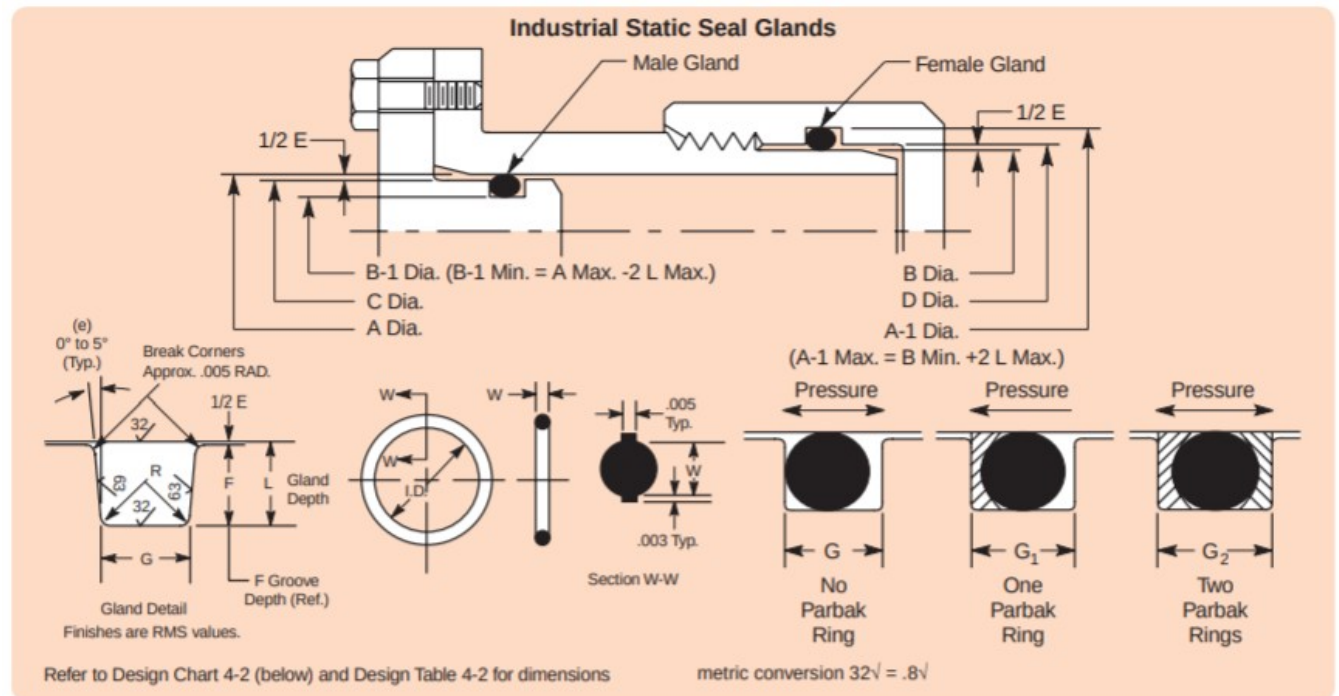
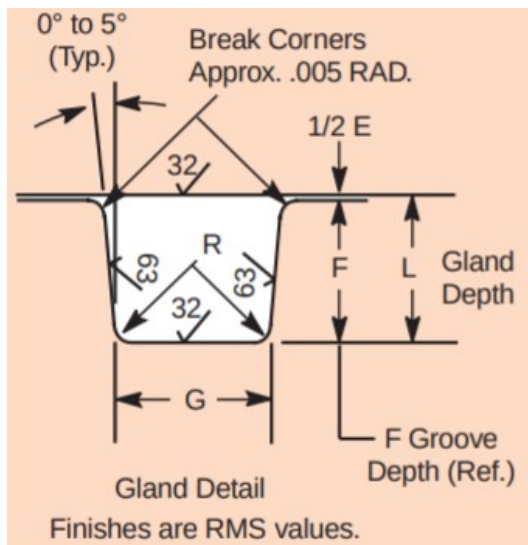
Fastening

- screws
 - no sockets, recesses, or slots
- threads
- glue (Master Bond EP42HT-2MED)



Sealing

- O-rings



Guide for Design Table 4-2

If Desired Dimension is Known for	Select Closest Dimension in Column	Read Horizontally in Column	To Determine Dimension for
Bore Dia. male gland	A	B-1 C G	Groove Dia. (male gland) Plug Dia. (male gland) Groove width
Plug Dia. male gland	C	A B-1 G	Bore Dia. (male gland) Groove (male gland) Groove width
Tube OD female gland	B	A-1 D G	Groove Dia. (female gland) Throat Dia. (female gland) Groove width
Throat Dia. female gland	D	A-1 B G	Groove Dia. (female gland) Tube OD (female gland) Groove width