Stage -01

Data (A)	Suitability Criteria
S-02	Appropriate Device (D)
	Appropriate Device Application (A)
	Appropriate Patient Group (P)
	Acceptable Report / Data Collection (R)

Data (B)	Contribution Criteria
S-03	Data Source Type (D)
	Outcome measures (O)
	Follow Up (F)
	Statistical Significance (S)
	Clinical Significance © (C)

Criteria of C

Oxford Level
Level I
Level II
Level III
Level IV
Level V

Description	Level	Gradiing System
Does the title contain exclusion criteria?	L1	Title exclusion
Does the abstract contain exclusion criteria?	L2	Abstract exclusion
Does the document contain exclusion criteria?	L3	Document exclusion
The document has been selected for L3 appraisal (CLIN) or for the description of the current state of the art (SOTA)	L4	Document inclusion
The document has appeared in a previous search	DUP	Duplicate

Description Criteria of Suitability (IMDRF MDCE WG/N56FINAL:2019)	Grading System	
Were the data generated from the device in question?	D1	Actual Device
	D2	Comparable device
	D3	Other
	NA	None
Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same Use
	A2	Minor Deviation
	A3	Majpr Deviation
	NA	None
Where the data generated from a patient group that is representative of the intended treatment population e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1	Applicable
	P2	Limited
	P3	Different Population
	NA	None
Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
	R2	Minor deficiencies
	R3	Insufficient information
	NA	None

Description Appraisal Criteria for Data Contribution (IMDRF MDCE WG/N56FINAL:2019)	Grading System	
Was the design of the study appropriate?	Level I to Level V	
Do the outcome measures reported reflect the intended performance of the medical device?	O1	Yes
	O2	No
Is the duration of follow up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
	F2	No
Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
	S2	No
Are the conclusions drawn well-founded and are no potential sources of error speculated?	C1	Yes
	C2	No

ontribution: Oxford level of Evidence (March 2011)

Point Value
5 (Very Good Study)
4
3
2
1 (Poor Study)

Selection Req
D1
D2
A1
A2
P1
P2
R1
R2

Selection Req
Level I to Level IV*
O1
F1
S1
C1
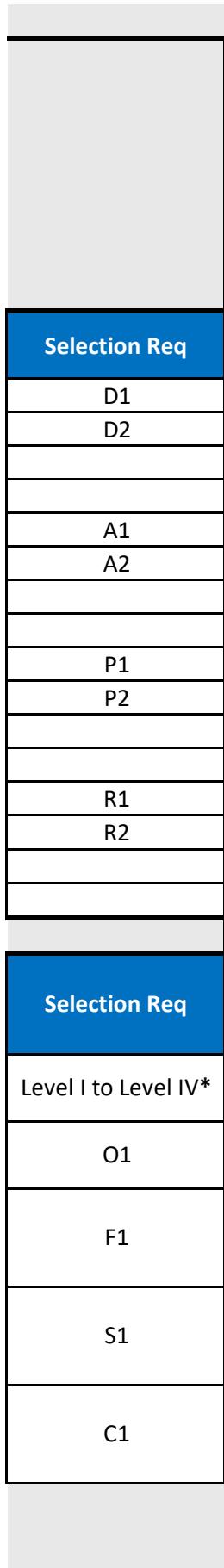
SL.No	PMID
1	

Mention the unique ID mentioned on the paper.

Title of the Article

Mention the title of the paper

Authors	Keywords

Mention the Authors of the paper   Mention the keyword/search term used

Publication Date (YEAR-MON-DD)	Database	Study Type	S-01
			Level
Mention the year of publication	Mention the platform/ source from where the paper was taken from e.g. sciencedirect or Pubmed etc	Mention the study type e.g. observational study, clinical trial…	L1/L2/L3/L3/D UP

S-02				Grad Value
Criteria of Suitability				
D	**A**	**P**	**R**	
D1/D2/D3/NA	A1/A2/A3/NA	P1/P2/P3/NA	R1/R2/R3/NA	Accepted/NA

S-03			
Appraisal Criteria for Contribution			
D	**O**	**F**	**C**

I/II/III/IV/V/No   Yes/No   Yes/No   Yes/No

Final Acceptance	Remarks for Inclusion or Exclusion
Accepted/Rejected	Mention the reason for Rejecting/ Accepting the paper